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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,959	12/27/2001	Mordechay Beyar	AMS-036	9503

7590 10/29/2004

American Medical Systems, Inc.  
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EXAMINER

JACKSON, GARY

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/034,959	Applicant(s) BEYAR, MORDECHAY	
	Examiner Gary Jackson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-13, 16-19, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 7-9, 14-15 and 20-22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*AG*

### DETAILED ACTION

This action is a response to applicant's amendment filed July 19, 2004. The arguments has been considered however, they are not persuasive to overcome the rejection.

The indicated allowability of the claims is withdrawn in view of reconsideration of the art of record to Lou (US Patent 5,328,077) and Benderev et al (US Patent 5,611,515). Rejections based on the references cited follow.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 10, 13 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou. The patent to Lou discloses a method of treating urinary stress incontinence by inserting a bone anchor into the wall of the pubic bone. It is well known in the art to provide a suture sling in order to support the bladder neck and urethra in a urinary stress incontinence procedure. It would have been obvious to one having ordinary skill in the art to utilize a suture/sling in Lou's procedure. Concerning claims directed to sensory feedback, such feedback is inherent when applying fasteners with hand held devices. It is inherent that one would feel the change in force in the handle, trigger or elsewhere when the mechanical action is completed or the fastener has been dislodged.

The dependent claims that were rejected are not entitled to the benefit of the earlier filing date and the narrower claims are not patentable over the art of record.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Benderev et al (US Patent 5,611,515).

Claims 11-13, 16, 17 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sohn et al (US Patent 5,988,171). The patent to Sohn et al discloses the limitations of the above claims including a visual indicator device. The visual indicator limitation is not entitled to the benefit of an earlier filing date before the Sohn et al June 1997 filing date. See response below.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 17 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,592,610 in view of Sohn et al. The US Patent '610 discloses the limitation of the above except for the visual limitation recitations. However, the Sohn et al patent discloses a similar device and method as

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recited in the above claims including a visual indicator. It would have been obvious to one having ordinary skill in the art to provide Patent '610 with visual indicators as taught by Sohn et al. so as to recognize when the fastener has been fully inserted or released from the inserter.

### *Allowable Subject Matter*

Claims 7-9, 14-15 and 20-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Response to Arguments*

Applicant's arguments filed July 19, 2004 have been fully considered but they are not persuasive. The arguments directed to in the specification by the applicant concerning recitation visual sensory limitation is not persuasive. Applicant point to the fact the since the suture is secured to the fastener, the suture will twist as the fastener is rotated; indication the fastener has been inserted is that the twisting has stopped. It is not inherent that the suture will twist because of the rotation of the fastener. Twisting on the suture depends on several factors including the amount of slack in the suture, the number of rotations of the fastener and the manner in which they are connected. The patent to Sohn discloses such visual indicators before the applicant's earlier filed patent 5,972,000. Further, this application is a continuation-in-part of said patent. The examiner believes that the visual indicator of twisting is a portion of the new matter added in the later filed application now US Patent 6,334,446.

For these reasons the examiner believes the action is proper.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (571) 272-4697. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Antoine Nguyen can be reached on (571) 272-4693. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson  
Primary Examiner  
Art Unit 3731



gj  
October 25, 2004